

# RESEARCH PROTECTIONS UPDATE

*News and Comment on the Protection of Human Subjects in Navy and Marine Corps Research*

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## *Comment*

### **HRPP for the Corps**

On January 21, 2011, Lieutenant General George Flynn, then-Deputy Commandant, Combat Development and Integration, U.S. Marine Corps, signed Marine Corps Order 3900.18 establishing a Marine Corps Human Research Protection Program (HRPP). Release of the order was the culmination of an extended and deliberate process of defining the scope and direction of a Marine Corps program.

Drafting the order validated the unique place the Corps occupies in the DON and endorsed the serious work Marine Commands had been doing to protect human research subjects.

Today, the Marine Corps HRPP addresses a wide range of research protocols at Marine Corps Combat Development Command, Systems Command, Operational Test & Evaluation Activity, Manpower & Reserve Affairs, and others.

Marine Corps research involving human subjects crosses an extensive range of initiatives, many, if not most of which are aimed primarily at finding new tactical capabilities for individual Marine units from the platoon to the battalion level. In recent years, Corps Commands have either conducted or provided direct support for programs in such areas as operator and weapon/sensor

system integration; human factors engineering; protective clothing and devices; combat casualty care and management; reduction of non-battle injuries; among others.

In these and other mission areas, the Corps has worked with a number of extramural (non-government) institutions as well as government laboratories to explore potential roles for an active denial system and sensors capable of “seeing” through walls, evaluation of the bioeffects of repeated low-level blast exposure, and a multi-mission personnel carrier (called the “G-wagon”).

Marine Corps research with human subjects has looked at methodologies for profiling potential terrorists; virtual marksmanship training; countermeasures against improvised explosive devices; and many others. In some ways, the Corps’ mission as America’s “911 force” capable of rapidly inserting combat-ready forces by air and sea into hostile environments shapes its research focus. Marine Corps Commands are oriented to Fleet/Force combat readiness, expressed by the motto, “every Marine a rifleman.”

That orientation was a critical factor as the Marine Corps program evolved, prior to and following the

release of General Flynn’s order. Marine commanders operating at sea, in deserts, or jungles, focus on mission effectiveness. Those Marines expect, as they should, that the Corps’ HRPP processes and procedures will be as lean and efficient as the units they support.

The DON HRPP also is engaged in that mission: ensuring that human subjects participating in Marine Corps-sponsored research are covered by the same safeguards as those involved in work supported by any Navy Command. As Marine combat units take care of their own on the battlefield, the Corps’ HRPP is doing the same in the laboratory.

#### **Also in this Issue:**

***FOCUS on U.S. Marine Corps: Senior officers of the Marine Corps Combat Development and Integration Branch of Headquarters, Marine Corps discuss the Corps’ planning for the “over the horizon” future.***

***COMNAVSEA signs out HRPP instruction***

***Yasenchak takes over interim Education and Training Role.***

Director's Notes

## Marine Corps HRPP: On Board with DON

By CAPT Alan F. Nordholm

The following pages provide feature articles on the important work of two newly minted organizations, the Futures Directorate and Capabilities Development Directorate within the Marine Corps Combat Development and Integration (CD&I) branch of Headquarters Marine Corps.

Like the Navy and the other Services, the Corps is confronting a complicated future with regard to its longstanding missions, as a result of vast geopolitical and strategic change and sharp fiscal constraints that likely will persist for years.

As we report, Deputy Commandant for CD&I Lt. Gen. Richard P. Mills directed far-reaching changes to the way the Corps crafts its vision of the future strategic environment and the combat options it will need in future conflicts. It's fair to say that the Corps is bracing for a future of change.

With regard to protection of research subjects, though, things are settling down for the Corps. As reported in our page 1 *Comment*, then-DC/CD&I Lt. Gen. George Flynn signed out the USMC program with Marine Corps Order 3900.18 in January 2011, citing the Department of the Navy HRPP Instruction, SECNAVINST 3900.39D, as its primary reference.

The order, drafted in the form of the traditional Marine Corps five-paragraph order for small-unit

leaders, directs USMC research managers to ensure that Marine Corps-sponsored research with human subjects reflects DON HRPP policy for research review, informed consent, training, reporting of serious incidents, and all other major components of policy. Marine Corps officials at the Quantico-based Commands have moved out smartly to implement the order, with the effect of implementing DON policy. The Marine Corps Combat Development Command and Systems Command, among others, are on board with DON HRPP. A Marine Corps IRB has been stood up and is reviewing research.

Challenges of executing HRPP continue as the Marine expeditionary units (MEUs) deployed in hot spots worldwide rely more heavily on the advanced technologies and systems developed by the Corps' research activities. Key elements of that work involve human subjects.

While the need to field new tactical capabilities becomes more critical, I can report that Marine Corps HRPP, operating within DON HRPP, continues to carry out its own mission to diligently oversee this work. No daylight exists between the Corps and the DON HRPP leadership on the importance of protecting research subjects.

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## NAVSEA Approves HRPP Instruction

Vice Admiral W. H. Hilarides, Commander, Naval Sea Systems Command (NAVSEA) last month signed out NAVSEA Headquarters Instruction 3900.12, standing up the Command's Human Research Protection Program.

NAVSEA, with a workforce of 60,000 government civilians, military personnel, and contractors at 33 facilities in 16 states, manages more than 160 acquisition programs for the Navy's surface and undersea force, including construction of all ships

and submarines, as well as shipboard weapon, combat system, and hull, mechanical, and electrical systems.

The Instruction "establishes policy for protection of the rights and welfare of human subjects involved in research conducted or supported by NAVSEA, including NAVSEA directorates, staff codes, warfare centers, field activities, and affiliated Program Executive Offices (PEOs)."

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Marine Corps CD&I

## CD&amp;I's Futures Team Brainstorming "How We'll Fight"

*The Combat Development & Integration branch of Headquarters Marine Corps has started a far-reaching reorganization aimed at enhancing the Corps' ability to evaluate future strategic scenarios in which Marines can expect to deploy, and then develop the combat capabilities they will need.*

*The reorganization, directed by Lt. Gen. Richard P. Mills, Deputy Commandant for CD&I, started in April and is expected to be complete by December. The new CD&I structure includes the Futures Directorate, an Analysis Directorate, a Joint Capabilities Assessment and Integration Directorate, and the Capabilities Development Directorate. Col. Tim Parker, Deputy Director of the new Futures Directorate and Col. Greg Ryan, Deputy for the Capabilities Development Directorate met with Research Protections Update to describe the challenges the Corps confronts.*

Futures Directorate Deputy Director Col. Tim Parker says that the reorganization is based on a need to more effectively coordinate futures planning by "maximizing the potential of all personnel" engaged in planning and assessments of the future security environment (FSE).

The Futures Directorate will be composed of new Futures Assessment and Emerging Force Development teams and the Marine Corps Warfighting Laboratory, which oversees science and technology programs and conducts wargames, live-force experiments, and simulations.

**Planning Strategy**

A top priority of the new Directorate, Parker says, is developing a strategic plan that will map out how the Corps should explore and evaluate all aspects of the FSE in the next several decades.

USMC/M. CALLAHAN



*3<sup>rd</sup> Marine Regiment Marines fire a shoulder-mounted assault weapon during Exercise Cobra Gold 2013 in Thailand.*

The Directorate will conduct analyses aimed at identifying potential enemies and allies and their combat capabilities. As part of that effort, the Directorate will look at trends in allocation and distribution of resources, such as crude oil, water, and critical minerals, such as rare-earth materials essential for production of semiconductors.

A top priority will be continuing assessments of the impact of changes in patterns of population growth and density. He points out, for example, that major population shifts have occurred along the world's shorelines, leading to dramatic increases in urbanization in coastal areas.

"That means that the next time we land, we won't land on a beach like Iwo Jima, but in a city like New York. We have to start thinking about how we fight in that environment," Parker says.

Parker explains that the Marine Corps will continue to carry out its traditional mission of "seizing and defending advanced naval bases," even while the Corps will operate with all the Services.

"Crisis response is still our 'sweet spot,'" he says. In particular, "we have to ensure that anything we do, we do with the Navy."

He explains that as operations in Afghanistan end, most Marine units will return to the expeditionary role, forward-deployed either aboard ship or ashore. Forces that had been moved from the Pacific theater to support the Afghanistan conflict will be sent back there as part of DoD's "strategic pivot" in the Pacific, which will require a larger Marine

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Marine Corps CD&I**Brainstorming “How We’ll Fight”***(Continued from page 3)*

Corps-Navy presence in Australia and elsewhere in the western Pacific.

The renewed focus on forward presence, Parker says, will require Marine expeditionary units (MEUs) to engage with allies in anticipation of

USMC/J. LAMB



*Pivot to Pacific: U.S. and Indonesia Marines conduct training during Cooperation Afloat Readiness and Training 2013.*

potential crises.

“A large U.S. presence is looked on in many parts of the world as an occupation force. We can tread lightly by leveraging with the Navy to allow most of the force to remain at sea.”

MEUs on station aboard ship also will collaborate with the Special Operations Command and the Coast Guard for fast-response maritime operations.

Assessments of future challenges will address all these priorities, Parker says, as well as the development—and affordability—of new technologies and systems that support Corps operations.

He points out that V-22 Osprey tiltrotor aircraft provides the range and speed for moving Marines to combat zones from amphibious shipping hundreds of miles from shore.

The Osprey, which has proven its value in Afghanistan operations, provides a new dimension for insertion of landing forces that offers greater flexibility than either helicopters or landing craft.

The Corps also will field the F-35B Lightning short takeoff/vertical landing or STOVL joint-strike

fighter to replace the AV-8B Harrier STOVL attack aircraft, preserving and extending the capability to provide close-air support to ground units. The Corps also plans to develop a new amphibious combat vehicle to replace older amphibious landing craft.

To ensure MEU effectiveness, Parker says, the Marine Corps also must work with the Navy in developing sea-basing doctrine, and on the design of new ships that can accommodate Marine equipment and vehicles.

USMC/C. STONE



*The V-22 Osprey tiltrotor aircraft provides a long-range fast-response option for moving Marines to combat.*

The Futures Directorate initiative adapts well-understood Marine Corps doctrines of Operational Maneuver from the Sea and Ship to Objective Maneuver, which establish tactics, techniques, and procedures for advancing on combat objectives by air and sea, beyond the traditional understanding of a beach as the objective.

Parker says that the Directorate builds on these doctrines as it aims at “one coherent story” for the Marines in coming decades. That story represents the top-level concept of “littoral maneuver” for the long term that integrates new combat assets, including those based on new technologies, as well as innovations in tactics, command and control, intelligence, logistics, and integration with Navy, joint-service, and allied forces.

Marine Corps CD&I

## CDD: Building the Future Corps

Col. Greg Ryan, Deputy Director of the Capabilities Development Directorate within Marine Corps CD&I, says that his team “develops warfighting capabilities that will provide for “an effective, integrated Marine air-ground task force (MAGTF), current and future, that anticipates strategic challenges and opportunities for the nation’s defense.”

The MAGTF is the Marine Corps’ baseline deploying force, a combined self-sustained ground-air-logistics team that “hits the ground running,” for fast-response combat operations without need for initial external support.



*The Corps continues to focus on expeditionary operations. Here, an amphibious assault vehicle debarks during a California exercise.*

Ryan’s CDD, which will remain basically unchanged through the reorganization of CD&I now underway (see page 3), will work closely with CD&I’s Futures Directorate to determine the shape of the future Corps.

“They [Futures] develop what the contingency might be. We’re the ones who try to develop capabilities that can be fielded, at the appropriate time, place, and at the appropriate cost, to meet that emerging requirement,” Ryan says.

### **Ground-Side Requirements**

“We work requirements for the Marine Corps—we work the ground side, basically, developing requirements for material and non-material solutions, that create capabilities that respond to the

Corps’ needs,” Ryan says. Material solutions include weapon systems and vehicles; non-material encompasses tactical/operational concepts and doctrine.

He says that CDD also is tasked with integrating those capabilities across all functions of the MAGTF, which means working hand-in-hand with the Deputy Commandant for Aviation, who is responsible for all MAGTF aviation components.

The CDD engages in a “capabilities-based planning process,” according to Ryan, using such tools as an expeditionary force development system (EFDS) and joint capabilities integration and development system or JCIDS. Over the past decade, CDD coordinated solutions to the Corps’ urgent needs for the wars in Iraq and Afghanistan.

That role meant meeting the emerging requirements in theater by getting combat capabilities into Marines’ hands quickly. This mission, Ryan says, spans the spectrum of doctrine, organization, training, materiel, leadership and education, personnel, and facilities, or DOTMLPF.

CDD also provides experts in warfighting areas and force capabilities and operations to the Navy and other Services to support acquisition initiatives, integration or coordination for joint programs, for example, integration of command and control systems, procedures, and tactics.

### **Integration Challenges**

Beyond supporting current warfighting needs, the CDD’s critical mission on the non-material side includes concept development, which encompasses modifications and enhancements to Corps doctrine.

For that role, the Directorate is organized into integration divisions (IDs) that oversee the development of requirements for mission areas: fires and maneuver; intelligence; force protection; cyber and electronic warfare; logistics; command and control; small wars and irregular warfare; and a new sea-basing integration division, which moved to CDD in the reorganization.

Each of the integration divisions addresses major

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Marine Corps CD&I***CDD: Building the Future Corps****(Continued from page 5)*

focus areas. For example, the logistics ID looks at ammunition, motor transport, test/maintenance, and calibration; deliberate engineering, and naval support. Intel encompasses the Marine Corps Intelligence Surveillance Reconnaissance Enterprise; intel doctrine; and persistent intel, surveillance, and reconnaissance, among others.

USMC/C. STONE



26<sup>th</sup> MEU Marines fire M4 carbines during an exercise.

The force protection ID addresses support for the warfighter and force protection capability development. Fire and maneuver covers ground combat and vehicle modernization and sustainment; unmanned aircraft systems and other initiatives.

A MAGTF integration division, Ryan says, oversees the integration of capabilities among mission areas as they are developed by the functional divisions.

CDD's Program Objective Memorandum (POM) branch uses a warfighting investment program evaluation board (WIPEB) to oversee funding for the requirements-development work by CDD's integration divisions and for systems acquisition for the Corps, although Marine Corps Systems Command manages USMC acquisition.

CDD's total force structure division (TFSD) defines the Corps' active and reserve forces and civilian workforce, and maintains tables of organization and equipment (TO/TE), which dictate the equipment breakdown for the battalion.

**End-Strength Pressures**

Ryan says that "we are looking at a current Marine Corps end-strength of 182,000 personnel, as established by the Commandant (down from 202,000). To be capable of conducting forcible-entry missions with two Marine Expeditionary Brigades (MEBs), the Corps must have 'x' number of infantry and armor battalions and helo and fixed-wing tactical aircraft squadrons."

Requirements for 1,000 Marines for MAR(SOC) special-ops units and personnel to support CYBERCOM place new strains on end strength.

"Those numbers flow to the TFSD, which determines, for example, how many armor and infantry officers are needed, as well as types and numbers of weapons and other systems, down to inventories of ammunition for training. The CDD then develops the required TOs and TEs to create the total Marine Corps force structure to meet the two-MEB forcible-entry requirement." Ryan says.

Currently, CDD's "major themes" are: (1) challenges of the DoD POM process, which dictates resources available for acquisition and force structure; (2) integration of ground and air assets of the MAGTF to preserve the Corps' rapid air-ground deployment capability; and (3) use of a Marine Corps force development system, an analytical process for identifying needs and structuring them as requirements.

**Lightening the Force**

Another theme is the difficult "reconstitution" of Marine forces. Ryan explains that "As we pull out of Iraq and Afghanistan, we're dealing with 10 to 12 years of wear and tear on our gear and our people. It will take investments in money, time, effort, and refocus away from the ground war to the strategic pivot back to the Pacific, back to our maritime roots and more amphibious flexibility."

An important aspect of reconstituting, he says, is lightening the MAGTF force. He points out that the Corps has grown heavy in the past 10 years. Prior to Iraq and Afghanistan, the individual Marine carried

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Marine Corps CD&I***“We Have to Make Very Difficult Decisions”****(Continued from page 6)*

about 60 pounds. Today the Marine carries around 120 pounds, including body armor, advanced helmets, radio systems and batteries, GPS receivers, and other devices. The new data systems increase the Marine’s situational awareness, but increase his load tremendously.

“The Marine who had to carry that heavy equipment in the [Middle East] desert could not do so in the jungles of Southeast Asia,” Ryan says.

The Corps is coordinating with the Army on research on lighter body armor, and looking at lightweight radios and rechargeable batteries.

The Corps also must load its gear on the Navy’s amphibious assault ships. MRAP (mine-resistant ambush-protected) vehicles used in Iraq and Afghanistan don’t fit on ships, and future joint light tactical vehicles (JLTVs) cannot exceed a certain height to fit into ship welldecks. These constraints require the Corps’ ground combat vehicle strategy to tie in with Navy ship design.

“We’re dealing with the design of ships that will be in service for 40 years,” Ryan says. “If we buy an ACV (amphibious combat vehicle) five years from now, it’s going to be around for 30 years.”

As part of the effort to lighten the MAGTF, the

Corps is divesting itself of most of its MRAPs.

The ground combat vehicle strategy, which Ryan says is well along in development, encompasses the JLTV, ACV, and a future Marine personnel carrier. The program faces fiscal constraints, but the Corps plans to keep its armor capability, now three battalions of M1A1 tanks, two active and one Reserve.

**Integration Challenges**

Ryan emphasizes that all the CDD themes—POM challenges, reconstitution, lightening the MAGTF, ground combat vehicles and others—as well as the key focus areas of all the integration divisions—are not “single lanes,” but are closely linked.

“The bottom line for CDD is that we have to make very difficult decisions on where we’re going to invest, sustain, and modernize. There’s always a tradeoff between modernization and sustainment.

“The CD&I reorganization is based on a ‘timeline continuum’ out 30 or 40 years,” Ryan says.

“The Futures guys are developing the CONOPS for 30 years from now. They build that timeline back to us. We develop the capabilities to address the current environment and, in conjunction with MARCORSSYSCOM, to field those capabilities for the Marines of today and tomorrow.”

Education and Training**Yasenchak Assumes E & T Duties**

Research Compliance Specialist Patti Yasenchak, DON HRPP’s coordinator for extramural research, has assumed the role of interim Education and Training Specialist for DON HRPP, following the departure of Christy Borders, who received a Meritorious Civilian Service Award for her work.

Yasenchak has an extensive background in education and research. After earning her B.A. and her M.Ed. at the University of Virginia, she joined the UVA School of Medicine faculty as research project coordinator for UVA’s Spinal Cord Injury Project. Later she was named director of education

for the American Academy of Orthotists and Prosthetists in Alexandria, Va.

While serving as clinical data coordinator and clinical research associate for PRA International in Charlottesville, she saw firsthand the importance of education and training as a means of ensuring compliance in research. Later, she was appointed clinical research coordinator at the Clinical Trials Office of the UVA Cancer Center. She joined the DON HRPP’s Research Protections Division at ONR in 2007.

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## NAVSEA Approves Command-Level HRPP Instruction

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Dr. Robert Fagan will serve as the NAVSEA Headquarters principal HRPP point of contact and Human Research Protection Official (HRPO).

Several of the NAVSEA warfare centers, including the Dahlgren (Va.), Panama City (Fla.), and Carderock (Md.) divisions of the Naval Surface Warfare Center (NSWC), and the Newport R.I., division of the Naval Undersea Warfare Center, (NUWC.), as well as the Navy Experimental Diving Unit, already hold approved Assurances, maintain their own Institutional Review Boards, and have developed and approved Command-level HRPP instructions.

DON HRPP Research Compliance Specialist Terrence Clemmons, who supports NAVSEA headquarters and the NSWC Dahlgren, Carderock, and Panama City divisions, says that the new NAVSEA instruction provides top-level policy guidance for all NAVSEA Commands.

It also may be used by those NAVSEA warfare centers and other research sites, for example, the NSWC Crane (Ind.) division or NUWC (Keyport, Wash.) that have not established HRPPs.

According to NAVSEAINST 3900.12, those Commands may either establish their own IRBs, or seek review of their research by means of an Institutional Agreement for IRB Review by an institution holding a DoD Assurance that maintains an IRB.

The new Instruction applies to “all human subject research conducted in the development, testing, or evaluation of any platform, system, subsystem, component, piece of equipment, or other materiel, even if a person is *not* the direct object of the research.” It extends to all NAVSEA personnel and personnel in affiliated PEOs who participate in, conduct, support, review, approve, or manage human subject research.



## Yasenchak Steps into E&T Role

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*Patti Yasenchak*

Yasenchak has participated directly in helping to guide DON HRPP’s education and training program. She worked closely with Borders in developing training for researchers at some 300 extramural institutions that perform DON-supported

research with human subjects, including the nation’s most prestigious research laboratories.



*Christy Borders*

“HRPP training is critical, not only to comply with the law, but also to fulfill our fundamental duty to the human subjects who support DON research,” she says.

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